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### ***published in***

Stroke

2000

### ***DOI (link to publisher)***

[10.1161/01.STR.31.10.2396](https://doi.org/10.1161/01.STR.31.10.2396)

### ***document version***

Publisher's PDF, also known as Version of record

### [Link to publication in VU Research Portal](#)

### ***citation for published version (APA)***

Snels, I. A. K., Beckerman-Boiten, H., Twisk, J. W. R., Dekker, J., Koning, P., Koppe, P. A., Lankhorst, G. J., & Bouter, L. M. (2000). Effect of triamcinolone acetonide injections on hemiplegic shoulder pain: a randomized clinical trial. *Stroke*, 31, 2396-401. <https://doi.org/10.1161/01.STR.31.10.2396>

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*Stroke* 2000, 31:2396-2401

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ISSN: 1524-4628

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# Effect of Triamcinolone Acetonide Injections on Hemiplegic Shoulder Pain

## A Randomized Clinical Trial

Ingrid A.K. Snels, MD; Heleen Beckerman, PT, PhD; Jos W.R. Twisk, PhD; Jos H.M. Dekker, MD; Peter de Koning, MD; Peter A. Koppe, MD; Gustaaf J. Lankhorst, MD, PhD; Lex M. Bouter, PhD

**Background and Purpose**—Hemiplegic shoulder pain is not uncommon after stroke. Its origin is still unknown, and although many different methods of treatment are applied, none have yet been proved to be effective. We sought to study the efficacy of 3 injections of intra-articular triamcinolone acetonide on pain and arm function in stroke patients with hemiplegic shoulder pain.

**Methods**—In a multicenter, randomized, placebo-controlled clinical trial, patients with hemiplegic shoulder pain received either 3 intra-articular injections of 40 mg triamcinolone acetonide or 1 mL physiological saline solution (placebo). Primary outcomes were pain measured according to 3 visual analogue scales (score range, 0 to 10), and arm function was measured by means of the Action Research Arm test and the Fugl-Meyer assessment scale; secondary outcomes were passive external rotation of the shoulder and general functioning measured according to Barthel Index and the Rehabilitation Activities Profile.

**Results**—In the triamcinolone group (n=18), the median decrease in pain, 3 weeks after the last injection, was 2.3 (interquartile range, 0.3 to 4.3) versus 0.2 (interquartile range, -0.5 to 2.2) in the placebo group. This result was not statistically significant. The change in the other outcome measures did not differ significantly between the 2 treatment groups. Twenty-five patients reported side effects.

**Conclusions**—In the 37 participants included in this study, triamcinolone injections seemed to decrease hemiplegic shoulder pain and to accelerate recovery, but this effect was not statistically significant. Therefore, on the basis of the results of this study, these injections cannot be recommended for the treatment of patients with hemiplegic shoulder pain. (*Stroke*. 2000;31:2396-2401.)

**Key Words:** clinical trials ■ hemiplegia ■ shoulder pain ■ stroke ■ triamcinolone

The occurrence of hemiplegic shoulder pain varies from 16% to 84% in stroke patients.<sup>1-8</sup> These patients remain hospitalized for a longer period of time, and shoulder pain interferes with the rehabilitation process.<sup>6,8</sup> Many different methods of treatment are applied for hemiplegic shoulder pain,<sup>2,9,10</sup> and many different preventive measures are also recommended.<sup>2,6,7,11-14</sup>

The clinical presentation of hemiplegic shoulder pain mimics that of the frozen shoulder (adhesive capsulitis). Recently, 2 reviews on the effectiveness of corticosteroid injections for shoulder disorders (in nonhemiplegics) have been published. Van der Heijden et al<sup>15</sup> found some indications for a positive effect of steroid injections for shoulder disorders, while Green et al<sup>16</sup> concluded that these injections improve the abduction in patients with rotator cuff tendinitis, but that no conclusion can be drawn about their effectiveness for patients with a frozen shoulder. However, in clinical practice,

physiatrists frequently treat patients with hemiplegic shoulder pain with steroid injections.<sup>10</sup> In a small, uncontrolled study, Dekker et al<sup>17</sup> found a positive effect of 3 intra-articular injections with triamcinolone acetonide (a corticosteroid) in 5 of 9 stroke patients with hemiplegic shoulder pain. However, the question of whether these injections are more effective than placebo injections remains unsolved. Therefore, a randomized clinical trial was conducted to evaluate the effect on pain and arm function of 3 intra-articular injections of triamcinolone acetonide versus placebo injections in patients with hemiplegic shoulder pain after stroke.

## Subjects and Methods

### Design

In a multicenter, placebo-controlled clinical trial, patients were randomized into 2 groups on the basis of computerized random numbers. Four strata were defined: rehabilitation centers versus

Received May 10, 2000; final revision received June 23, 2000; accepted June 23, 2000.

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nursing homes and onset of stroke shorter or longer than 6 months before the trial. For the treatment allocation, numbered sealed envelopes were used. Patients received either 3 injections with triamcinolone acetonide (40 mg Kenacort A-40 in 1 mL) or 3 placebo injections (1 mL saline solution). The patients and all other people involved, except for the injecting physicians, were blinded for the type of treatment. Although an attempt was also made to blind the injecting physicians, this was not possible. Therefore, in no case was an injection given by the physiatrist who was treating the patient. One week before treatment commenced only pain was measured, and 1 week later all baseline measurements were performed, followed by randomization and the first injection. The third measurement took place 1 week after baseline, immediately before the second injection. Two weeks after the second injection the fourth measurement took place, immediately before the third injection. The follow-up measurements took place 3 and 9 weeks after the third injection.

## Subjects

Inclusion criteria were as follows: (1) hemiplegia after stroke, (2) pain in the hemiplegic shoulder  $\geq 4.0$  (on a scale of 0 to 10) on at least 1 of 3 visual analogue scales (VAS) during at least 2 weeks, (3) a limitation of the passive external rotation of the hemiplegic shoulder of  $>20^\circ$  compared with the other (unaffected) side, (4) age 18 to 80 years, and (5) written informed consent. The most important reasons for exclusion were an injection in the affected shoulder during the previous 6 months or use of systemic corticosteroids during the previous 3 months, other obvious explanation for the pain (eg, fracture, luxation), earlier surgery of the involved shoulder, severe communication problems ( $<P50$  on the *Stichting Afasie Nederland* test),<sup>18</sup> or severe cognitive problems ( $\leq 20$  on the *Mini-Mental State Examination*).<sup>19</sup> Patients were initially recruited from 2 rehabilitation centers, but after 6 months, an insufficient number of patients had been included. Therefore, patients were recruited from 4 additional rehabilitation centers, the rehabilitation wards of 3 nursing homes, and a stroke patient organization. The research protocol was approved by the ethics committees of all participating institutions.

## Treatment

The injections were given by experienced physicians via the posterior route.<sup>20</sup> After each injection the patients were provided with a sling for the rest of the day, but no further changes were made in their normal rehabilitation program.

## Measurements

### Baseline Measures

In addition to demographic and medical characteristics (type of stroke, side of lesion in the cerebrum, side of hemiplegia, comorbidity), the following prognostic factors were measured at baseline. The grade of subluxation of the shoulder was rated from an x-ray film of the affected shoulder in an anteroposterior projection, as described by Van Langenbergh and Hogan.<sup>21</sup> Sensory disorders were dichotomized: any sensory deviation reported by the patient in a test involving touching or pin-pricking of the arms, or in a test for vibration disorders with a tuning fork on the distal end of the radius, was rated as abnormal. Visual field deficits were tested by means of the direct confrontation method.<sup>22</sup> Neglect was measured according to a letter cancellation test and a line bisection test and was defined as the difference between right and left of  $>2$  missed *O*'s on a letter cancellation test or  $<34$  *O*'s canceled of 40, or a mean deviation of  $>+7.9$  mm for neglect of the left side or  $>-6.1$  mm for neglect of the right side on a line bisection test that consisted of 10 lines of 10 cm. Similar tests are described elsewhere.<sup>23,24</sup> Spasticity was assessed during passive motion in the elbow joint and rated according to the Ashworth scale.<sup>25</sup> The presence or absence of a shoulder-hand syndrome was rated according to the criteria of Tepperman et al.<sup>26</sup>

### Primary Outcome Measures

Pain was measured according to 3 vertical VASs of 10.0 cm each: pain today, pain during the day in the previous week, and pain during the night in the previous week.<sup>27,28</sup> The bottom of the scale was no pain at all, and the top was very severe pain. The outcome measure was calculated as the mean of the pain scores during the day and during the night in the previous week. The arm function was assessed by means of the Action Research Arm test,<sup>29,30</sup> which consists of 19 items focusing on grasping objects of different shapes and sizes and gross movements of the arm (score range, 0 to 57). The Fugl-Meyer assessment scale for the upper extremity and coordination (32 items; score range, 0 to 66) was used to assess the impairment level of the arm function.<sup>31</sup> In both the Action Research Arm test and the Fugl-Meyer assessment scale, a higher score indicates a higher functional level.

### Secondary Outcome Measures

The passive range of external rotation of the shoulder was measured with a fluid-filled goniometer.<sup>32</sup> The functional level of the patients was measured according to the Barthel Index<sup>33</sup> (10 items; score range, 0 to 20) and 4 domains of the Rehabilitation Activities Profile: communication, mobility, personal care, and occupation.<sup>34</sup> The Rehabilitation Activities Profile score was calculated as the percentage of the maximum possible score for each patient. For both the Barthel Index and the Rehabilitation Activities Profile, a higher score indicates a lower functional level. After each injection, the injecting physicians were asked how sure they were that the injection was intra-articular. All cointerventions and side effects were recorded.

## Statistical Analysis

The greatest difference between the 2 treatment groups was expected to be found between baseline and the first follow-up, which took place after 3 weeks. Therefore, for every patient the absolute change in the outcome scores between baseline and the first follow-up measurement was calculated, so that a positive difference indicated improvement for the patient. Because of the small number of patients in both groups and the skewed distribution of the differences between the 2 groups, a nonparametric test (Mann-Whitney *U* test) was used, with the exact method used to calculate the *P* values. The level of statistical significance was set at 0.05. Median differences between the groups and the 95% CIs were calculated.<sup>35</sup>

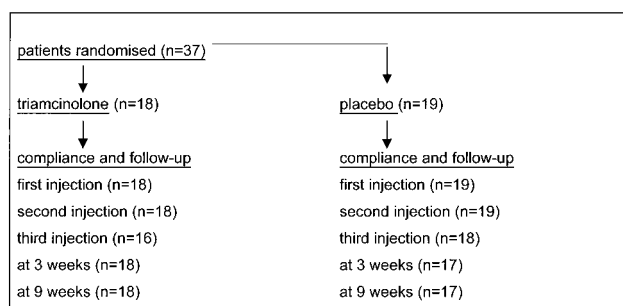
Additional analyses were applied to identify specific subgroups in which the results differed from the overall results. These subgroups were based on sex, type of lesion, side of hemiplegia, involvement of the dominant side, time since onset of stroke, time since onset of hemiplegic shoulder pain, recruitment source, sensory disorders, visual field deficits, neglect, spasticity, cointerventions, and comorbidity. SPSS 9.0 for Windows 95 was used for these analyses.

A DOS version of Spida was used to calculate the Generalized Estimating Equations (GEE) for repeated measures in an additional analysis, with the mean pain during the previous week as outcome. Interaction between the treatment group and time was also studied. The advantage of GEE is that the data of all 6 measurements are included. However, with a small number of patients the point estimator becomes less reliable.

A priori, the minimal clinically important difference (MCID) between the treatment groups were defined as follows: for pain, the MCID was a decrease of  $\geq 30\%$  in the total range of the scale on the VAS for pain during the previous week; for the Action Research Arm test, Fugl-Meyer assessment scale, and Rehabilitation Activities Profile, the MCID was a difference of 10% in the total range of the scale; for the Barthel Index, the MCID was a difference of  $\geq 4$  points of 20.<sup>33</sup>

## Results

Figure 1 shows that 37 patients were randomized. Twenty-seven patients were recruited from 6 rehabilitation centers, 8 from 3 nursing homes, and 2 from a stroke patient organization. Two patients in the triamcinolone group did not receive the third injection but completed the follow-up measure-



**Figure 1.** Randomization, compliance, and follow-up of patients.

ments. In the placebo group, 2 patients dropped out because the injections had insufficient effect: 1 after 2 injections and the other after 3 injections.

Table 1 shows the baseline characteristics of the included patients. Despite randomization, sex and side of lesion were not equally distributed over the 2 groups. None of the patients suffered from a shoulder-hand syndrome. No differences were found in the use of preventive measures (supportive sling, lap board) or in the number of patients who received additional physiotherapy or occupational therapy for their shoulder. At baseline the groups did not differ with regard to the outcome variables (Table 2). Because of logistic problems, the x-ray films, which were taken to evaluate the degree of subluxation, were of insufficient quantity and quality, and therefore this variable could not be included.

The course of pain over time is presented in Figure 2. In none of the measurements did the pain scores differ significantly between the groups. The use of GEE also showed no significant difference between the 2 treatment groups. The distributions of the other primary outcomes were too skewed to warrant application of GEE.

Table 3 shows the results of the nonparametric tests for all outcome measures. No significant or clinically relevant differences between the 2 groups were found.

**TABLE 1. Patient Characteristics at Baseline**

	Triamcinolone (n=18)	Placebo (n=19)
Age, mean (SD), y	60.6 (8.4)	62.5 (10.6)
Sex, F/M	6/12	12/7
Type of lesion, hemorrhage/infarction	4/14	5/14
Side of hemiplegia, right/left	9/9	5/14
Involvement of dominant side	9	7
Time since onset of stroke, <6 mo/≥6 mo	11/7	13/6
Time since onset hemiplegic shoulder pain, <6 mo/≥6 mo	12/6	14/5
Sensory disorder	11	8*
Visual field deficits	3	3
Neglect	7*	7*
No hypertonia (Ashworth 0–1)	7	9
Hypertonia (Ashworth 2–4)	11	10
Cointerventions	10*	14
Comorbidity (diabetes mellitus)	15 (3)	16 (4)

\*One case missing.

**TABLE 2. Outcome Measures at Baseline**

	Triamcinolone (n=18)	Placebo (n=19)
Pain previous week (VAS)	5.1 (4.2 to 6.3)	4.0 (2.5 to 6.6)
Action Research Arm test	0 (0 to 17)*	0 (0 to 31)
Fugl-Meyer	6.5 (4 to 44.3)	12 (4 to 49)
Passive external rotation, °	20 (−1.3 to 36.3)	10 (0 to 30)
Barthel Index	4 (3 to 10.3)	6 (2 to 9)
Rehabilitation Activities Profile, % of maximum possible score	52.1 (40.1 to 64.6)	54.2 (45.8 to 60.8)

Values are median (interquartile range).

\*One case missing.

In the subgroups of patients with no sensory disorders, pain decreased by 3.6 in the triamcinolone group and by 0.3 in the placebo group (median difference, 2.7; 95% CI, 0.6 to 5.1). In patients with no visual field deficits, pain decreased by 3.0 in the triamcinolone group and increased by 0.1 in the placebo group (median difference, 2.3; 95% CI, 0.3 to 4.4) and in patients with no neglect pain decreased by 3.3 in the triamcinolone group versus 0.5 in the placebo group (median difference, 2.2; 95% CI, 0.1 to 4.4). In other subgroup analyses, however, some significant differences with no biologically plausible explanation were found (data available from the author on request). For the secondary outcome measures (passive external rotation of the shoulder, Barthel Index, Rehabilitation Activities Profile), no significant differences were found.

The results concerning correct placement of the injections are presented in Table 4. According to the injecting physicians, 51% of the triamcinolone injections were certainly intra-articular versus 30% of the placebo injections. This difference of 21% is statistically significant (95% CI, 3% to 40%).

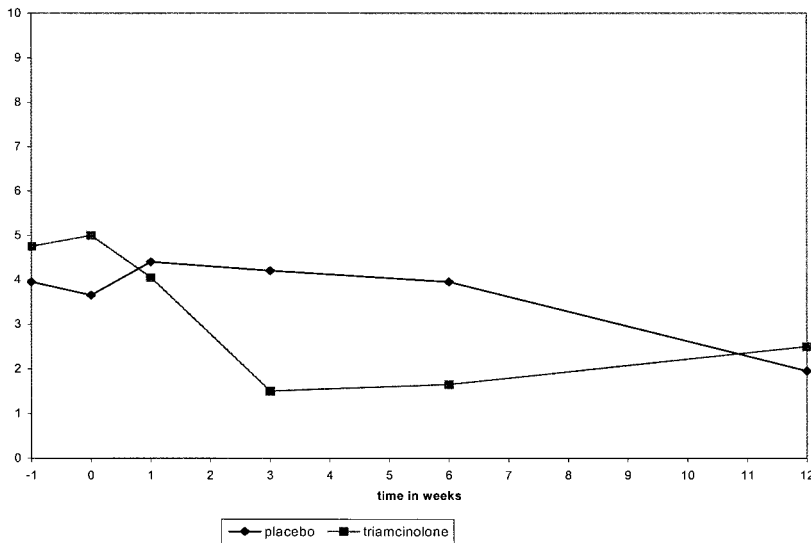
After the last measurement, the blinded outcome assessor guessed the applied treatment correctly in 21 of 35 cases (60%): 11 of 17 cases (65%) of the placebo group and 10 of 18 cases (56%) of the triamcinolone group.

Twenty-five patients reported 1 or more side effects: 12 of these patients were treated with triamcinolone injections and 13 with placebo injections. Table 5 presents the reported side effects. In the patients with diabetes, no disturbances of the blood glucose level were detected.

## Discussion

Before recruitment commenced, it was calculated that at least 35 patients in each group would be needed to obtain sufficient power to detect a statistically significant and clinically relevant reduction in pain. A power calculation based on the available data<sup>36</sup> revealed a power of 0.5 for detecting the predefined minimum clinically relevant difference in pain improvement. Therefore, the small number of patients in-





**Figure 2.** Median pain scores during the study period; the injections were given at weeks 0, 1, and 3.

cluded in the study may be the main reason why the effect of the intervention on pain was not statistically significant. The recruitment of patients from various sources may have diluted the results in 2 different ways. First, recruitment of patients from various sources probably introduced additional factors that could have interfered with the experimental treatment but could not be controlled for. Second, the increase in the number of recruitment sources also increased the number of injecting physicians (in total, 16 different physicians were involved).

The effect of intra-articular injections was studied, and the reported number of intra-articular injections given differed in the 2 groups (Table 4). Although it has been reported that intra-articular corticosteroid injections are more effective than non-intra-articular injections,<sup>37</sup> the clinical importance of this finding is unclear.<sup>38</sup> Therefore, it can be assumed that this difference between the groups did not influence the outcomes of the study.

To measure pain, 3 VASs were used: pain today, pain during the day in the previous week, and pain during the night in the previous week. Patients were included if they rated their pain  $\geq 4.0$  on  $\geq 1$  of these 3 scales at the first and second measurements. The effect of the intervention was based on the mean pain score during the previous week. There was no difference in effect between the 13 patients who rated their mean pain during last week  $< 4.0$  and the 24 who rated their pain  $\geq 4.0$ . Although the VAS is a generally accepted and validated instrument to measure pain and other subjective feelings,<sup>27,39–41</sup> several researchers have recently reported problems when applying a VAS to stroke patients.<sup>42–44</sup> These findings were confirmed in the present study: several patients had serious problems with understanding the VAS and how to complete it. However, an additional question about pain, which could easily be answered by the patients, revealed similar results (data not shown).

Pain in the shoulder and limitation of the passive movements of the shoulder, especially of the external rotation, are

**TABLE 3. Median Improvement 3 Weeks After Last Injection**

	Triamcinolone* (n=18)	Placebo* (n=17)	Mann-Whitney <i>P</i>	Median of Differences† (95% CI)
Pain (VAS)	2.3 (0.3 to 4.3)	0.2 (−0.5 to 2.2)	0.06	1.9 (−0.1 to 3.7)
Action Research Arm test	0‡ (0 to 1.0)	0 (0 to 3.8)	0.17	0 (−3.0 to 0)
Fugl-Meyer	3.5 (0 to 8.0)	1.0 (0 to 3.8)	0.41	2.0 (−1.0 to 5.0)
Passive external rotation, °	2.5 (−11.3 to 21.3)	0 (−10.0 to 10.0)	0.71	4.3 (−14.3 to 25.0)
Barthel Index	1.5 (0 to 3.3)	1.0 (−5.0 to 4.0)	0.85	0 (−2.0 to 2.0)
Rehabilitation Activities Profile, % of maximum possible score	15.9 (2.1 to 21.4)	6.3 (−6.3 to 17.1)	0.17	7.5 (−3.0 to 15.3)

\*Positive numbers indicate improvement of the patient.

†Positive numbers indicate a greater effect in triamcinolone group than in placebo group.

‡One case missing.

**TABLE 4. Reported Location of Injections**

	Triamcinolone (n=18)*	Placebo (n=19)†
Injection intra-articular?		
Yes, positive	26	16
Yes, probable	23	38
Yes, possible	2	0

\*A total of 52 injections were given, 1 missing.

†A total of 56 injections were given, 2 missing.

the clinical signs on which the diagnosis of capsulitis of the shoulder is based.<sup>45</sup> However, pain and a limitation of the external rotation of the shoulder are sometimes attributed to spasticity of the shoulder muscles.<sup>3,6,7,13</sup> When spasticity is the main cause of pain, it is unlikely that triamcinolone will have a significant effect. It is difficult to distinguish between pain in the limited hemiplegic shoulder based on capsulitis alone, pain based on spasticity alone, or a combination of these.

Recurrent injuries allegedly maintain a capsulitis.<sup>46,47</sup> Patients with sensory disorders, visual field deficits, or neglect have a higher risk of recurrent injuries of the shoulder, possibly resulting in capsulitis, and triamcinolone injections will not resolve this problem. The subgroup analyses in this study seem to confirm this hypothesis, but the number of patients in these subgroups was very small, and therefore no firm conclusions can be drawn.

The absolute change scores were used as an outcome measure. Statisticians disagree on whether it is preferable to use relative change scores<sup>48</sup> or absolute change scores.<sup>49</sup> However, there is agreement that an absolute outcome without correction for baseline differences would not be appropriate. In this study analysis was performed with both absolute and relative change scores, and similar results were found. Because absolute change scores are more easily interpreted, these are presented.

**TABLE 5. Reported Side Effects\***

	Triamcinolone (n=18)	Placebo (n=19)	Total
More pain in shoulder for <1 d	3	9	12
More pain in shoulder for 1–2 d	1	1	2
More pain in shoulder for >2 d	5	5	10
Local skin lesion	3	0	3
Postmenopausal hemorrhage	1	0	1
Flushing	4	1	5
Other	12†	6‡	18
Total	29	22	51

\*Twenty-five patients reported side effects: 13 in the placebo group and 12 in the triamcinolone group.

†Stiffness of the arm (2), diarrhea (1), pain in leg and decrease in walking ability combined with pain in homolateral arm (2), feeling feverish without increase in body temperature (1), dry mouth (2), collapse (1), hematoma on the arm (1), dropping foot (1), unknown (1).

‡Cold hands and feet (1), soreness of the left upper quadrant of the ventral thorax (1), pain in hand (1), fatigue in arm (1), cramping pain in fingers (1), cyst in inguinal region (1).

It was very surprising that it was so difficult to find patients with hemiplegic shoulder pain, which suggests that the occurrence rates reported in the literature should be reexamined. In recent years much emphasis has been placed on the prevention of hemiplegic shoulder pain in the Netherlands, and it seems that the problem is becoming less common. However, if a patient develops hemiplegic shoulder pain, the question of the manner of treatment remains unanswered. No significant effect of triamcinolone injections was found, and side effects were frequently reported (although most of these were not serious). A new and larger randomized trial should be executed to draw definite conclusions about the efficacy of triamcinolone injections and to identify subgroups of patients for whom these injections are effective. However, on the basis of the results of this study, intra-articular triamcinolone injections cannot be recommended for the treatment of hemiplegic shoulder pain.

### Acknowledgments

This research project was funded by the Netherlands Organization for Scientific Research, Council for Medical and Health Research (NWO-MW). We are very grateful for the compliance of the patients who participated in this study. We also thank the physicians who introduced the executive investigator to the patients and the physicians who gave the injections.

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